

I. AMENDMENT

A. Specification:

Kindly amend the specification as follows:

On page 3, in line 2, change “allows” to – alloys --.

B. Drawing:

Submitted with this Response is a drawing, identified as Figure 1. The drawing is the same as that submitted in the provisional application (S.N. 60/179,494) on which priority is based. The drawing is referred to on page 6, line 10 as illustrating the configuration of an ultrasonic probe used in that example. The drawing should have been included with the application as originally filed, but was inadvertently omitted.

Accordingly, no new matter has been added by the submission of the drawing as requested.

II. REMARKS

A. Election/Restriction Requirement:

The Office Action contains an election/restriction requirement between the claims of Group I (i.e., Claims 1-15 and 24-31) “drawn to an ultrasonic applicator” and Group II (i.e., Claims 16-23) “drawn to a method of making an ultrasonic applicator.” (Office Action, ¶’s 1-3).

Applicant confirms the oral election of the Claims in Group I -- with traverse.

The Office Action asserts that the subject matter of the Claims in Group I and the Claims in Group II are distinct because the “process as claimed can be used to make other and materially different product such as a scalpel . . .” (Office Action, ¶ 3.) With all

due respect, such an assertion is incorrect, because the claims of Group II clearly require the making and fabrication of an “ultrasonic applicator” in both the preamble and recited steps of the claim. Accordingly, a process for forming an ordinary scalpel would not fall within the scope of the Claims in Group II. Thus, the claims in this case are clearly related and not distinct.

Accordingly, applicant respectfully submits that the election/restriction requirement is improper and requests that it be withdrawn.

B. Drawings:

The Office Action requests that a drawing be submitted to facilitate understanding of the invention. In response applicant has submitted a drawing, i.e., “Figure 1,” as identified in the specification at p. 6, line 10 in referencing the shape of the probe used in the example. As noted previously, this drawing was included in the provisional patent application from which priority is claimed. The drawing was apparently omitted inadvertently from the present application when submitted to the Patent Office.

Thus, applicant has satisfied the Office Action’s requirement for a drawing.

C. Specification:

Applicant has amended the application at age 3 of the specification as requested by the examiner. Applicant appreciates the examiner’s having noted this typographical error.

The examiner also requested that the reference to Figure 1 be deleted on p. 6, line 10 of the specification. As noted previously, the drawing appears to have been inadvertently omitted when this application was submitted to the Patent Office. In

compliance with the Office Action requirement for a drawing, the omitted drawing has been submitted with this response.

D. Claim Rejections – 35 U.S.C. Sec. 112:

The Office Action asserts that Claims 6, 7, 10, 11, 14, 15, 29 and 30 are indefinite because the thickness of the surface coating is different (i.e., “between about 0.0001 and 0.0003 inch”) in the parent claims than it is in the dependent claims (i.e. “between about 0.0003 and 0.0005 inch” as recited in Claims 6, 10, 14 and 29). Applicant respectfully submits that there is no ambiguity. The specification makes it clear that: “The coating should be thicker when it contains a dye or colorant because the color will not be visible if the coating is too thin. The thinner clear coating is preferred over the thicker colored coating for this reason.” Read in light of the specification, there should be no ambiguity in the interpretation of these claims.

E. Claim Rejections – 35 U.S.C. Sec. 103:

All of the pending claims in this application have been rejected under 35 U.S.C. Sec. 103 as being unpatentable over the Hood patent (i.e., U.S. Patent No. 5,935,143) in view of Rhandhawa (U.S. Patent No. 4,981,756). The Office Action provides the following basic, rationale for the rejection:

Hood ‘143 discloses an ultrasonic applicator or knife for use by surgeons formed of a base portion of aluminum alloy (see column 7, line 49) and of a surface coating of ceramic material or aluminum oxide (see column 7, line 53). With respect to claims 1, 8, 12 and 24 Hood ‘143 does not teach that the aluminum oxide coating be of a thickness of between 0.0001 and 0.0003 inch. Rhandhawa teaches old and well known the use of ceramic material coatings of a thickness of from 1 to 10 microns on medical tools (see claim 3). To modify the applicator of Hood /143 such that the thickness of the aluminum oxide coat is between 0.0001 and 0.0003 inch would have been obvious since one of ordinary skill in the art of coated medical devices at the time of the invention would readily have recognized such

coating thickness as being within an effective coating thickness range for providing wear resistance in the manner of the coatings of Rhandhawa.

(Office Action, p. 4, ¶ 11.)

Preceding this quoted rationale, the Office Action paraphrases the U.S. Supreme Court's long-standing criteria for analyzing obviousness set forth in Graham v. John Deere, 383 U.S. 1, 148 U.S.P.Q. 459 (1966). But the Office Action fails to follow that process.

Among other things, the Office Action fails to determine the scope and content of the prior art – the initial step required by the Supreme Court. In particular, the Office Action fails to determine what is prior art. Both the present application and Hood discuss some of the many complicated issues that must be resolved in the design of a successful ultrasonic surgical instrument. While the use of ultrasonic vibrations can, in general, facilitate certain medical procedures, the use of ultrasonic vibrations cause many technical issues such as: (a) how to deliver the ultrasonic energy to the operative site; (b) how to minimize damage to adjacent tissue and (c) how to create a durable surgical instrument. Technical issues such as these are not involved in non-ultrasonic devices. Thus, prior art relevant to claims 1, 8, 12 and 24 of the present invention is prior art relating to “an ultrasonic applicator for an ultrasonic surgical device” – not prior art relating to “medical devices” in general.

While the Hood '143 Patent relates to one form of ultrasonic device, it does not disclose the subject matter of applicant's claimed invention. The portion of the Hood disclosure cited in the Office Action actually discloses a number of different possible base materials with a number of possible, different coatings. Admittedly, aluminum alloy is among the base materials, and aluminum oxide is listed among the possible surface

coatings. But there is no disclosure of the use of aluminum alloy with aluminum oxide, there is no disclosure of using a high-strength aluminum alloy and there is no disclosure of using an aluminum oxide surface coating having the claimed thickness. The Office Action fails to acknowledge and address all of these differences between the Hood '143 Patent and the claimed invention.

The Office Action only acknowledges that Hood fails to teach the claimed thickness of the surface coating. To cure this deficiency the Office Action cites the Rhandhawa Patent, which shows a broad range of aluminum oxide surface coatings on a scalpel. The Office Action concludes that because applicant's claimed thickness range falls within that of Rhandhawa, it would have been obvious to one of ordinary skill in the art. This logic is not correct. Rhandhawa is not relevant prior art. It relates to a simple surgical device, i.e., a scalpel, that is not ultrasonic. Indeed, the Office Action's concedes that the scalpel of Rhandhawa is a "materially different product" than the subject matter of the claims at issue. (Office Action, p. 2, ¶ 2, last sentence.)

The Office Action mistakenly justifies the motivation to employ the teaching of Rhandhawa with that of Hood by asserting that they both relate to medical devices and that one would use a surface coating within the thickness range taught by Rhandhawa, because that would provide "wear resistance." (Office Action, p. 4, ¶ 11; emphasis added.) This purported logic emphasizes the deficiencies in attempting to combine these two references to reconstruct applicant's claimed invention. To follow the logic of the Office Action and the purported teaching of Rhandhawa would result in the use of a thicker coating for increased wear of an ultrasonic device. In fact, among other features of the claimed invention, applicant has discovered that it is important to use a thinner

coating of aluminum oxide in an ultrasonic surgical device. Neither the Hood '143 Patent nor Rhandhawa recognizes or teaches this.

Among other things, applicant has found that a simple or general coating of aluminum oxide significantly reduces the ultimate strength and the yield strength by reducing the cyclic fatigue strength. This happens because the brittle ceramic layer on the outside (coating) is prone to cracking as the applicator expands and contracts during vibration. Because the coating is part of the outer surface of the aluminum alloy applicator this produces many small cracks in the outer surface. The cracks become "stress concentrators," little zones in the material that concentrate the vibratory stresses above those that would be expected for an uncracked surface. This results in a decrease in fatigue strength, meaning that the vibratory amplitude must be reduced in order to maintain a reasonable lifetime for the applicator. The thicker the ceramic coating the worse this problem becomes. Thus, applicant has found that a "very thin" aluminum oxide coating, properly controlled for thickness, can reasonably solve this problem and further, provides a more biocompatible surface than the simple aluminum alloy.

Thus, the general recitation of long lists of possible materials in Hood and the non-analogous teachings of Rhandhawa with respect to a simple scalpel do not, and cannot, render applicant's claimed invention obvious to one of ordinary skill in the art.

Because the fundamental premise for the rejection of the independent claims is unwarranted, applicant does not address the other distinctions over the prior art added by the dependent claims, but reserves the right to do so later, if necessary. Applicant does note that many of the features of the dependent claims are asserted to be obvious without reference to any teaching in the prior art.

III. CONCLUSION

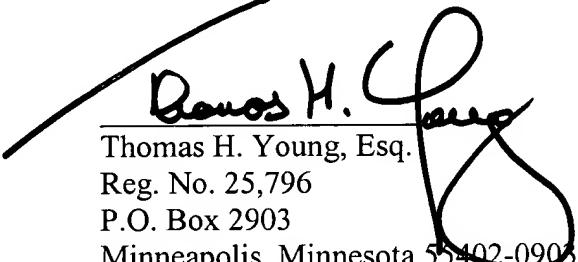
For all the foregoing reasons, applicant respectfully submits that this application is in condition for allowance, and such action is respectfully requested.

It is Applicant's belief that there are no fees or charges associated with this Response, other than the fee tendered in connection with the requested extension of timer. If however, applicant is in error, you are hereby authorized to charge any deficiency to Deposit Account No. 13-2725 with reference to Docket No. 40206.9-US-U1.

Respectfully submitted this 22nd day of May 2003.



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